510 (k) SUMMARY

SEP - 1 2011

ALP® 501 RB Pneumatic Compression System
510 (k) Number K112311

Applicant's Name:

Currie Medical Specialties Inc.
730 East Los Angeles Avenue
Monrovia, California 91762
Tel.: 626-303-3521
Fax: 626-303-3957

Contact Person:

Bernice Navarro, Vice President Quality Assurance
Currie Medical Specialties Inc.
730 East Los Angeles Avenue
Monrovia, California 91762
Tel.: 626-303-3521
Fax: 626-303-3957

Date Prepared:

July, 2011

Trade Name:

ALP® 501 RB Pneumatic Compression System

Classification Name:

Compressible Limb Sleeve

Classification:

Class II
Product Code: JOW
Regulation No. 870.5800

Statement of Substantial Equivalence:

The ALP® 501 RB Pneumatic Compression System is substantially equivalent in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available ALP® 501 Pump System. The changes between the two systems include the addition of an optional battery operated unit and change in inner components.

Device Description:

The ALP® 501 RB Pump is a prescriptive, pneumatic compression device designed to apply compression to the lower limb. The ALP® 501 RB pump is compact this making it a portable ambulant system. The ALP® 501 RB pump provides the user with an option of battery operation in addition to the operation from the mains option. The ALP® 501 RB pump is easy to use and provides the user with three treatment options: compression of the foot, compression of the calf, or combined compression of both (one foot and one calf).

The foot and calf compression program fills a garment bladder and decompresses. The device is composed of three main sub-systems:

1) A portable pneumatic pump unit,
2) A pair of garments (calf and/or foot) and
3) Pneumatic connecting tubes.

Inflation and deflation of the garments are controlled by the pump system. The inflation and deflation produces a massage on the patient limb in order to stimulate the natural flow of the body fluids.

Indications:

The ALP® 501 RB Pump System is a prescriptive device that induces controlled compression of the calf, the thigh, and the foot or combined compression.

The ALP® 501 RB Pump System is intended for use by patients and medical professionals in treating many conditions, such as:

- Reduce the incidence of deep vein thrombosis (DVT) and pulmonary embolism due to the presence of risk factors for thrombosis formation
- Enhancement of arterial blood flow
- Reduction of post-operative pain and swelling
- Reduction of compartmental pressure after tissue trauma

Contraindications:

The ALP® 501 RB Pump system should not be used in the following cases: Gangrene, recent skin graft, severe arteriosclerosis or other ischemic vascular disease, congestive cardiac failure, massive edema, pulmonary edema, existing DVT, acute thrombophlebitis, acute infections and during episodes of pulmonary embolism.

Performance Date:

A series of safety and performance testing including comparative analysis between the ALP® 501 RB Pump system and the ALP® 501 Pump System demonstrated that the ALP® 501 RB Pump System is substantially equivalent to the ALP® 501 Pump System without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Currie Medical Specialties, Inc.
c/o Ms. Bernice Navarro
Vice President Quality Assurance
730 East Los Angeles Avenue
Monrovia, CA 91762

SEP - 1 2011

Re: K112311
ALP® 501 RB Pneumatic Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 10, 2011
Received: August 11, 2011

Dear Ms. Navarro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112311

INDICATIONS FOR USE

510 (k) Number (if known): K112311

Device Name: **ALP® 501 RB Pneumatic Compression System**

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

510 (k) Number K112311

Prescriptive Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular Devices

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